

Notice of Allowability	Application No.	Applicant(s)	
	09/627,165	KIM ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/19/04.
2. ☒ The allowed claim(s) is/are 29,31 and 33.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date 19.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>0504</u>. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other <u>Christopher S. F. Low</u> |
|---|---|

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Art Unit: 1653

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lee Heiman on May 3, 2004.

Examiner's Amendments to the Specification:

Please replace the paragraph between lines 22-26 at page 4 with the following paragraph:

Figs. 1A-1B show the isolation of the lectin fraction KML-C from the protein fraction KM-AS derived from the Korean mistletoe extract of the invention through a hydrolyzed sepharose-4B column in a chromatogram (A) and in an electrophoresis pattern (B).

Please replace the paragraph between lines 1-2 at page 5 with the following paragraph:

Figs. 2A-2C show the cytotoxicity effects of KM-110 and KM-AS over B16-BL6 (A), Raji (B) and normal lymphocyte (C).

Please replace the paragraph between lines 5-6 at page 5 with the following paragraph:

Figs. 4A-4B show the response of the immuno-competent cell administered with KML-C to Con. A.

Please replace the paragraph between lines 7-8 at page 5 with the following paragraph:

Figs. 5A-5C show the IL-1 induction by KM-110 (A and B) and KM-AS (C).

Please replace the paragraph between lines 13-14 at page 5 with the following paragraph:

Art Unit: 1653

Figs. 8A-8C show the activity of KM-110, KML-C, EML-1 and C-free AS to secrete TNF- α , IL-C and IFN- γ .

Please replace the paragraph between lines 20-22 at page 5 with the following paragraph:

Figs. 11A-11B show NK-cell activity changes according to the administration period of time and concentration of KM-110.

Please replace the paragraph between lines 23-24 at page 5 with the following paragraph:

Figs. 12-1 and 12-2 show the NK-cell activity induced KML-C against the cell proliferation of YAC-1.

Please replace the paragraph between line 25 of page 5 and line 3 of page 6 with the following paragraph:

Figs. 13A-13D show the activity of KM-110 against tumor metastasis in Balb/c mice and C57BL/6 which are injected with KM-110 intravenously, subcutaneously, orally, and nasotracheally, two days before the transplantation of tumors.

Please replace the paragraph between lines 7-8 at page 6 with the following paragraph:

Figs. 15A-15B show the killing activity of mouse macrophage induced by KM-110 over B16-BL6 melanoma.

Please replace the paragraph between lines 12-14 at page 6 with the following paragraph:

Figs. 17A-17B show the inhibitory activity of KM-110 against tumor-dependent vascularization and tumor growth *in vivo*.

Art Unit: 1653

Please replace the paragraph between lines 15-16 at page 6 with the following paragraph:

Figs. 18A-18D show the effects of KM-110 and KML-C on the antibody production of KLH.

Please replace the paragraph between lines 17-19 at page 6 with the following paragraph:

Figs. 19A-19D show the sub-isotype analysis results of the KHL-specific antibodies induced by the immunization with KHL alone and in combination with KM-110.

Please replace the paragraph between lines 22-23 at page 6 with the following paragraph:

Figs. 21A-21B show the induction results of IL-2 and IL-4 from mouse splenocytes immunized with KLH.

Please replace the paragraph between lines 4-6 at page 7 with the following paragraph:

Figs. 24A-24B show the specific differentiation of splenocytes upon tumor vaccine and KM-110 alone or in combination.

Please replace the paragraph between lines 7-8 at page 7 with the following paragraph:

Figs. 25A-25B show the cross reaction of monoclonal antibodies 9H7-D10 and 8B11-2C5 with KML-C and EML-I.

Please replace the paragraph between lines 11-13 at page 7 with the following paragraph:

Figs. 27A-27B show the cross reaction of monoclonal antibodies 9H7-D10 and 8B11-2C5 with KML-IIU, KML-IIL and EML-I.

Art Unit: 1653

Please replace the paragraph between lines 21-22 at page 7 with the following paragraph:

Figs. 31-1, 31-2 and 31-3 show the comparison in the antibody production against HBV among KML-110, KML-IIU and KML-IIL.

Please replace the paragraph between lines 3-5 at page 8 with the following paragraph:

Figs. 33A-33B show the synergistic activity in anti-mycoplasma antibody production, induced by composite adjuvants containing KML-110.

Please replace the paragraph between lines 6-7 at page 8 with the following paragraph:

Figs. 34A-34B are standard curves based on Sandwich ELISA for KML-C(A) and KML-IIU (B).

Please replace Table 9a at page 50, lines 19-28 with the following Table 9a:

<A Chain>																																
II U				Y	E	R	L	K	L	Y	-	V	T	H																(SEQ ID NO: 24)		
II L				Y	E	R	L	R	L	R	-	V	T	H	Q	T	T	G	D	E	Y	F	R	F	I	T	L	L	R	D	(SEQ ID NO: 25)	
CI 6H															H	Q	T	T	G	D	E	Y	F	R	F	I	T	L	L	R	D	(SEQ ID NO: 26)
EMLA				Y	E	R	L	R	L	R	-	V	T	H	Q	T	T	G	E	E	Y	F	R	F	I	T	L	L	R	D	(SEQ ID NO: 27)	
RTA	I	F	P	K	Q	Y	P	I	I	N	F	T	T	A	G	A	T	V	Q	S	Y	T	N	F	I	R	A	V	R	G	(SEQ ID NO: 28)	
ABA				E	D	R	P	I	-	K	F	S	T	E	G	A	T	S	Q	S	Y	K	Q	F	I	E	A	L	R	E	(SEQ ID NO: 29)	
II U																															(SEQ ID NO: 30)	
II L	Y	V																													(SEQ ID NO: 31)	
CI	Y	V	S	S	G	S	F	S	N		E	I	P	L	L	R	Q	S	T	I	P	V	S	D	A	Q	R	F	V	L		

Art Unit: 1653

Examiner's Amendments to the Claims:

Please cancel claims 1-28 and 35-48.

Claims 31 and 33 have been amended as follows:

31. (Currently amended) The method of claim 29, wherein said KML-IIU has the amino acid sequence [SEQ.] SEQ ID NO: 16.

33. (Currently amended) The method of claim 29, wherein said KML-III has the amino acid sequence [SEQ.] SEQ ID NO: 14.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

May 3, 2004